FDA 101

FDA Public Workshop - Regulatory Science Considerations for Software Used in Diabetes Management

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What does FDA do?

What is regulation?

(hint – it isn't just premarket approval)

What is the value added of regulation?

What is the right balance?

Regulatory "bar": purpose and risk

- Some devices low risk – e.g., retrospective CGM analysis software
  - No premarket review
  - Design controls (for software), good manufacturing practices, adverse event reporting, etc. required
- Some devices are moderate risk – e.g., glucose meters, insulin pumps
  - Premarket review of 510(k) required
- Some devices are high risk – e.g., Artificial Pancreas devices
  - Premarket approval required (including premarket manufacturing inspection, change control)
- Some devices are under FDA enforcement discretion – e.g., data storage/display software
  - are legally "devices" but FDA allows marketing without any regulatory requirements

Goal = Balance

Premarket: Value Added

- **Premarket review**
  - Independent assessment of analytical and clinical validity
  - Does the device work for its intended purpose?
  - Does not require perfection – Benefit vs. Risks considered
- **Design control**
  - Focused process to ensure quality and safety
  - Device modifications deliberate and considered
- **Good manufacturing practices** – toward assuring consistency
- **Labeling requirements**: “truth in labeling”

Postmarket: Value Added

- **Assures accountability – Someone *is* responsible**
- **Manufacturing and Design**
  - Design control, Risk Assessment
  - Complaint handling
  - Corrective and Preventive Actions (CAPA)
- **Enforcement / Compliance**
  - Reporting injuries/deaths
  - Corrective actions/Recalls – to address device issues or remove devices from market
  - Inspections, WLs, seizures, injunctions, civil money penalties

Medical Device Design Control

- Low, Medium, and High risk devices
  - **Design Input**
    - Device requirements
  - **Design Output**
    - Documenting the result of the design effort
  - **Design Verification**
    - Design output meets design input requirements
  - **Design Validation**
    - Ensure devices conform to defined intended use
    - Software devices: Software validation
    - Risk analysis

Postmarket: Value Added

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  - Design control, Risk Assessment
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Complaints

- Must maintain complaint files
- Evaluated for reporting to FDA
- Complaints involving device defects are investigated

Corrective and Preventive Actions (CAPA)

- Complaints and other data sources that identify potential issues
- Root cause analysis of identified issues
- Actions to prevent recurrence

Postmarket: Value Added

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- Manufacturing and Design
  - Design control, Risk Assessment
  - Complaint handling
  - Corrective and Preventive Actions (CAPA)
- Enforcement / Compliance
  - **Reporting injuries/deaths**
  - **Corrective actions/Recalls – to address device issues or remove devices from market**
  - Inspections, WLs, seizures, injunctions, civil money penalties

Medical Device Reporting (MDR)

- Notification of Injuries/deaths
- MDR applies to: Manufacturers, User facilities, Importers

Device Issue Resolution

- Corrective actions and Product Recall
  - Actions without removal from market
  - Removal of the device from the market

Postmarket: Value Added

- Assures accountability – Someone *is* responsible
- Manufacturing and Design
  - Design control
  - Risk Assessment
  - Corrective and Preventive Actions (CAPA)
- Enforcement / Compliance
  - Reporting injuries/deaths
  - Corrective actions/Recalls – to address device issues or remove devices from market
  - **Inspections, WLs, seizures, injunctions, civil money penalties**

Enforcement by FDA

- **Inspections (also part of pre-market approval-High Risk and periodic inspection of device manufacturers)**
  - FDA physical presence at manufacturing site, regardless of where located
  - May result in warning letters or other letters
  - May result in Injunctions, seizures, or civil money penalties

Benefit:Risk

- High
- Med
- Low

Regulatory Oversight

- High
- Med
- Low
- Enforcement Discretion

How can the public help?

Report Directly to FDA

- Patients, healthcare professionals and consumers who find a problem related to a medical device are encouraged to report medical device adverse events or product problems to FDA through MedWatch, the FDA Safety Information and Adverse Event Reporting Program. Submit reports to FDA through the MedWatch program in one of the following ways:
  - Download the MedWatcher Mobile App - allows individuals to submit voluntary reports of serious medical device problems to the FDA using a smart phone or tablet
  - Complete the MedWatch Online Reporting Form - https://www.accessdata.fda.gov/scripts/medwatch/

Thank you!

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